UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/610,313	07/05/2000	Susan Barnett	PP01631.101	4221

27476 7590 10/05/2006

NOVARTIS VACCINES AND DIAGNOSTICS INC.
CORPORATE INTELLECTUAL PROPERTY R338
P.O. BOX 8097
Emeryville, CA 94662-8097

EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/610,313	BARNETT ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40 and 43-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *48-51* is/are allowed.

6)☒ Claim(s) *1-40 and 43-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-40 and 43-51 are pending.

Applicant's traversal and the amendment to claims 1 and 27 in paper filed on 7/21/06 is acknowledged and considered by the examiner.

It is acknowledged that in a previous office action, the examiner found applicant's argument persuasive and the 112 first paragraph written description and enablement was withdrawn. However, upon further consideration of the evidence of record, the 112 first paragraph rejection are reapplied in view of the breadth of the claims (The number of nucleotides in each SEQ ID NO: is at least 2457 nucleotides and thus at least 819 amino acids is encoded by each nucleotide sequence set forth in SEQ ID NOs: 30-32. The total number of 819 amino acid peptides is 1.85×10^{66}. The number of single amino acid substitutions is 15,561. The number of two amino acid substitutions is over 242,000,000. It is known for nucleic acids as well as proteins, for example, that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances), *In re Giolito*, 530 F.2d 397, 400, 188 USPQ 645, 648 (CCPA 1976), and that the claims do not commensurate with the guidance provided in the specification.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: The later-filed application must be an

application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Instant claims 1-40 and 43-51 do not enjoy priority to co-pending US application 09/475,704 because application '704 does not provide written support for SEQ ID NO: 30-32. Figures 8-10 recited in instant claim 1 are not disclosed in '704. The Figures in '704 only go up to Figure 6 and are directed to a HIV Gag polypeptide.

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-40 and 43-51 of this application. Neither provisional application 60/114,495 nor 60/152,195 provide written description for SEQ ID NO: 30-32 in instant claims 1-40 and 43-51.

Thus, the instant application only enjoys priority to 7/5/00.

Applicant's arguments filed 7/21/06 have been fully considered but they are not persuasive.

In response to applicant's argument that compliance with 112 first paragraph does not necessarily require that the priority applications set forth in *ipsis verbis* the terms and language recited in the claims, the argument is not found persuasive there is nothing in the priority applications that would direct the skilled artisan to the SEQ ID NOs: 30-32. "It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when

combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose." Lockwood v. American Airlines Inc., 41 USPQ2d 1961, 1966 (CAFC 1997).

In response to applicant's argument that the skilled artisan would recognize that all three priority applications describe and enable production of synthetic polynucleotide sequences encoding an HIV polymerase (see page 4, 10, Example 1 and Section 2.1.2 (page 28) of '704, page 5, 14, 38 of '195 and page 36 of '495, the argument is not found persuasive because there is no evidence of record to support applicant's assertion. In addition, the argument is not found persuasive there is nothing in the priority applications that would direct the skilled artisan to the SEQ ID NOs: 30-32. See Lockwood v. American Airlines Inc., 41 USPQ2d 1961, 1966 (CAFC 1997).

Claim Objections

Claim 47 remains objected to because of the following informalities: A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.

A claim, which depends from a dependent claim, should not be separated by any claim, which does not also depend from said dependent claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n). Claim 47 is separated from claim 2.

If the claims (including claim 47) become allowable the numbering of the claims would have to be amended.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-40 and 43-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-40 and 43-47 as best understood, are readable on a genus of a polynucleotide sequence encoding an HIV Pol polypeptide that elicits a Pol-specific immune response, and further wherein the polynucleotide sequence encoding said Pol polypeptide comprises a nucleotide sequence having at least 90% sequence identity to the sequence presented in SEQ ID NO: 30, 31, or 32, wherein the genus of polynucleotide sequences is not claimed in a specific biochemical or molecular structure that could be envisioned by one skilled in the art at the time the invention was made are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification contemplates production of a genus of a polynucleotide sequence encoding a polypeptide including an immunogenic HIV Pol polypeptide, wherein the polynucleotide sequence encoding said Pol polypeptide comprises a nucleotide sequence having

at least 90% sequence identity to the sequence presented in SEQ ID NO: 30, 31, or 32. The as-filed specification provides sufficient description of an immunogenic HIV Pol polypeptide set forth in SEQ ID NO: 30, 31, or 32. The specification does not define the term "an HIV Pol polypeptide that elicits a Pol-specific immune response". The specification defines an "immunological response" as humoral and/or cellular immune response (page 15) and the cellular immune response could include a response with CD4+ cells and/or CD8+ cells. The genus embraces a large number of polynucleotide sequences. The specification does not disclose which nucleotides are considered essential for eliciting a humoral and/or cellular immune response. For example, the specification does not disclose what peptides encoded by SEQ ID NOs: 30-32 contains a CTL epitope. The as-filed specification recites that the synthetic HIV Pol polynucleotides will be capable of higher protein production compared to wild-type HIV Pol polynucleotide sequences (page 36). The specification and the art of record teach that HIV Pol comprises the enzymes reverse transcriptase (RT) and integrase (INT). The specification states, "Because synthetic HIV-1 Pol expressed the functional enzymes reverse transcriptase (RT) and integrase (INT) (in addition to the structural proteins and protease), it may be helpful in some instances to inactivate RT and INT functions (page 73)." The claims recite a structure and a function (polynucleotide encodes an HIV polypeptide that elicits a Pol-specific immune response) for the genus of polynucleotide sequences. However, the function (immunogenic polypeptide) is a function common to almost all polypeptides. While, one skilled could envision a polynucleotide sequence that is at least 90% identical to the claimed SEQ ID NOs., the skilled artisan would be unable to determine based on the description in the specification if the sequence has a function (e.g., RT, INT activity, higher protein production than a wild type HIV Pol, etc.)

that is considered part of the claimed genus of DNA molecules. Thus, in view of the reasons set forth above and the numerous sequences embraced by the genus, the specification does not disclose which activities correspond to the claimed genus of polynucleotides with 90% sequence identity to the claimed SEQ ID NOs:.

It is apparent that on the basis of applicants' disclosure, an adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention and reference to potential methods and/or molecular structures of molecules that are essential for the genus of polynucleotide sequences as claimed; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of biochemical or molecular structures of polynucleotide sequences that must exhibit the disclosed biological functions as contemplated by the claims.

It is not sufficient for the specification to contemplate a genus of polynucleotide sequences to support the presently claimed invention directed to a genus of a polynucleotide sequence that encodes an HIV Pol polypeptide that elicits a Pol-specific immune response, wherein the polynucleotide sequence encoding said Pol polypeptide comprises a nucleotide sequence having at least 90% sequence identity to the sequence presented in SEQ ID NO: 30, 31, or 32. The claimed invention as a whole is not adequately described if the claims require essential or critical elements, which are not adequately described in the specification and which is not conventional in the art as of applicants' effective filing date. Claiming a genus of polynucleotide sequences that must possess the biological properties as contemplated by applicants' disclosure without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has

arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of a genus of a polynucleotide sequence encodes an HIV Pol polypeptide that must exhibit the contemplated biological functions, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods disclosed in the as-filed specification. Thus, in view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Applicant's arguments filed 7/21/06 have been fully considered but they are not persuasive for the reasons of record.

Applicant's arguments filed 5/16/05 have been fully considered but they are not persuasive.

In response to applicant's argument that the claims no longer read on sequences encoding Pol polypeptides, with all the various functions intrinsic to Pol polypeptides, the argument is moot because of the amendment to the claims.

The argument addresses both written description and enablement rejections at the same time. The examiner is not sure about whether some arguments are directed toward the written description and not the enablement and vice versa. "The written description requirement is

separate and distinct from the enablement requirement." See In re Barker, 559 F.2d 588, 194 USPQ 470 (CCPA 1977), cert. denied, 434 U.S. 1064 (1978); Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991). The examiner will do his best to respond to the arguments directed to written description and not enablement. In view of the prosecution history of the instant application, it appears that the majority of applicant's arguments against the written description rejection have already been addressed in prior office actions.

In response to applicant's that in view of appendix A (PowerPoint slides presented by Christopher Low at the BioScience Forum on Thursday, September 9, 2004) and Example 14 of the PTO's "Synopsis of Application of Written Description Guidelines" written description requirement is satisfied because the instant specification discloses examples of sequences having claimed activity and methods of determining the presence or absence of such activity.

Applicant's argument with respect to Appendix A is not found persuasive because the claim language embraces a genus of polynucleotides that encode an HIV Pol polypeptide that elicits a Pol-specific immune response. The specification does not provide sufficient description that a genus of HIV Pol polypeptides can elicit a Pol-specific immune response and have an HIV pol activity.

Applicant's argument to Example 14 providing support for the claimed invention is not found persuasive because the example is directed to a nucleotide sequence with 95% identity encoding a protein with a specific activity, which is narrower than the claims reciting 90% identity. The specification does not define what is considered to be a Pol-specific immune response.

Applicant argues that the correlation between polypeptide structure (primary sequence or tertiary structure) and immunogenic function can tolerate many modifications. In other words, whereas essential residues are readily identifiable for enzymatic (e.g., catalytic) functions, any polypeptide can tolerate multiple substitutions at various residues while still retaining its immunogenic function.

Applicant's argument is not found persuasive because there is no evidence of record supporting applicant's assertion that a nucleotide sequence (SEQ ID NOs: 30-32, which are at least 2,400 base pairs in length) can tolerate multiple substitutions at the DNA level and still retain its immunogenic function.

In response to applicant's argument that US Patent No. 6,602,705 has been issued with claims and disclosure highly analogous to those in the pending claim, the difference being that US Patent '705 claims polynucleotide sequences subtype C sequences and the guidance provided by this issued Patent regarding homology and assaying immunogenicity is virtually identical to that provided in the pending specification. Thus, '705 an issued and presumptively valid US Patent provides further evidence that the Patent Office considers claims such as those pending herein to be adequately described.

Applicant's argument is not found persuasive because every case is decided on its own merits. (*See In re Giolito*, 530 F.2d 397, 400, 188 USPQ 645, 648 (CCPA 1976):

"We reject appellants' argument that the instant claims are allowable because similar claims have been allowed in a patent. It is immaterial whether similar claims have been allowed to others." That other patents have been issued, based on different facts, is not evidence that the examiner's decision in this case, on these facts, is in error.

Claims 1-40 and 43-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an expression cassette comprising the polynucleotide sequence set forth in SEQ ID NOs: 30, 31, or 32, does not reasonably provide enablement for a polynucleotide sequence encoding an HIV Pol polypeptide that elicits a Pol-specific immune response, wherein the polynucleotide sequence encoding said Pol polypeptide comprises a nucleotide sequence having at least 90% sequence identity to the sequence presented in SEQ ID NO: 30, 31, or 32. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The invention lies in the field of producing a composition comprising an expression cassette comprising a nucleotide sequence encoding an HIV Pol polypeptide, wherein the polynucleotide sequences has at least 90% sequence identity to the sequence set forth in SEQ ID NOs: 30-32 and using the composition for generating an immune response in a subject.

The applicants contemplate: 1) Expression assays for the synthetic coding region of Pol, Env, and Gag-protease expression cassettes; 2) In vivo immunogenicity of Gag, Pol, and Env expression cassettes using plasmid DNA carrying the synthetic Gag, Pol, and Env expression cassette; 3) DNA immunization of non-human primates by administering intradermally, mucosally, bilaterally, intramuscularly into the quadriceps using various doses of a synthetic Pol, Env, and Gag-containing plasmid; 4) In vitro expression of recombinant alphavirus vectors or plasmid containing the synthetic Gag, Pol, and Env expression cassette; 5) In vivo

immunogenicity of recombinant Sindbis replicon vectors containing Gag, Env, and Pol expression cassettes in mice by using intramuscular and subcutaneous routes.

The specification further recites that these experiments will exhibit increased potency for induction of cytotoxic T-lymphocytes (CTL) response and humoral immune response by using the Gag, Pol, and Env expression cassettes.

The specification recites, "Because synthetic HIV-1 Pol expressed the functional enzymes reverse transcriptase (RT) and integrase (INT) (in addition to the structural proteins and protease), it may be helpful in some instances to inactivate RT and INT functions (page 73)."

The broadest claims read on a polynucleotide sequence encoding a Pol HIV polypeptide that elicits a specific Pol immune response (humoral and/or cellular) and is functional (maintains a functional Int, RT, protease, etc.) and is at least 90% sequence identity to the sequence presented in SEQ ID NO: 30-32. The as-filed specification does not provide sufficient guidance and/or factual evidence for one skilled in the art to make and/or use a sequence having at least 90% identity to any of the sequences presented as SEQ ID NO: 30, 31, or 32 other than the sequences themselves. The claimed invention embraces polynucleotide sequences encoding an HIV Pol that elicits a Pol-specific immune response and could have RT and INT activity, RT and/or INT activity and has other structural proteins and protease. The specification recites that HIV Pol comprises the enzymes reverse transcriptase (RT) and integrase (INT). The specification provides no guidance as to which (if any) of the amino acids may be changed while RT, INT, structural protein(s), protease activity are retained. The number of nucleotides in each SEQ ID NO: is at least 2457 nucleotides and thus at least 819 amino acids is encoded by each nucleotide sequence set forth in SEQ ID NOs: 30-32. The total number of 819 amino acid

peptides is 1.85×10^{66}. The number of single amino acid substitutions is 15,561. The number of two amino acid substitutions is over 242,000,000. It is known for nucleic acids as well as proteins, for example, that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. The specification does not provide sufficient guidance and/or factual evidence that it was routine to substitute or delete at least 240 nucleotides of a 2,400 nucleotide sequence and determine which nucleotide sequences meet the functional limitation of the claims. The effects of these changes is largely unpredictable as to which ones have a significant effect versus not. Several publications document this unpredictability of the relationship between sequence and function, albeit that certain specific sequences may be found to be conserved over polypeptides of related function upon a significant amount of further research. See the following publications that support this unpredictability as well as noting certain conserved sequences in limited specific cases: Baker et al., Science, 294:pages 93-96, 2001); Attwood, T (*Science*, vol. 290, no. 5491, pp. 471-473, 2000); Gerhold et al., (*BioEssays*, vol. 18, no. 12, pp. 973-981, 1996); Russell et al., *Journal of Molecular Biology*, vol. 244, pp 332-350, 1994); and Wells et al., *Journal of Leukocyte Biology*, vol. 61, no. 5, pp. 545-550, 1997). Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain immunogenic HIV Pol activity, and the fact that the relationship of the sequence of a peptide and its tertiary structure (*e.g.* its activity) are not well understood and are not predictable (Ngo et al. The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495), it would require an undue amount of experimentation for one skilled in the art in view of the prior art to arrive at other sequences that

have at least 90% sequence identity to an HIV polypeptide that elicits a Pol-specific immune response encoded by SEQ ID NOs: 30-32 and still possess any HIV polypeptide activity. Since it would require undue experimentation to identify other polypeptides that elicit a Pol specific immune response and retain the properties of a wild type HIV polypeptide, it certainly would require undue experimentation to make their corresponding DNA, and therefore, the entire scope of the claimed invention.

In conclusion, the instant specification and claims coupled with the art of record at the time the invention was made only provide sufficient guidance and/or evidence to reasonably enable making and using an expression cassette comprising the polynucleotide sequence set forth in SEQ ID NOs: 30, 31, or 32, does not reasonably provide enablement for a polynucleotide sequence encoding an HIV Pol polypeptide that elicits a HIV Pol specific immune response, wherein the polynucleotide sequence encoding said polypeptide comprises a nucleotide sequence having at least 90% sequence identity to the sequence presented in SEQ ID NO: 30, 31, or 32. One would have to engage in a large quantity of undue experimentation in order to practice the claimed invention based on the In Re Wands Factors including the lack of guidance in the application's disclosure, the unpredictability of producing nucleotide sequences encoding an HIV Pol polypeptide that elicits a Pol-specific immune response with 90% sequence identity to the claimed SEQ ID NOs.

Applicant's arguments filed 7/21/06 have been fully considered but they are not persuasive. In view of the In Re Wands Factors, the as-filed specification does not provide sufficient guidance for one skilled in the art to practice the full scope of the claimed invention.

Applicant's arguments filed 5/16/05 have been fully considered but they are not persuasive.

In response to applicant's argument that the presence of inoperative embodiments does not necessarily render a claimed nonenabled (See MPEP 2168.08(b) and In re Angstadt, 537 F.2d 498, 504, 190 USPQ 214, 219 CCPA 1976, In re Cook, 439 F.2d 730, 735, 169 USPQ 298, CCPA 1971; Horton v. Stevens, 7 USPQ2d 1245, 1247, Fed. Cir. 1998, the argument is not found persuasive for the reasons of record. See pages 19-20 of office action mailed on 6/14/04.

In response to applicant's argument that every single nucleotide species exhibiting 90% identity to SEQ ID NOs: 30-32 can be determined *a priori* and as such the entire genus of polynucleotides exhibiting 90% identity to these sequences is enabled by the specification as filed (See Example N of training materials for examining patent applications with respect to 112 first paragraph enablement.), the argument is not found persuasive because while one skilled in the art can envision every species exhibiting identity to SEQ ID NOs: 30-32, it would require an undue amount of experimentation to determine what species meet the functional limitations of the claims. The specification fails to provide sufficient guidance and/or factual evidence that it was routine for one skilled in the art to screen at least 1.85×10^{66} amino acid peptide for HIV pol peptides that meet or do not meet the limitations set forth in the claims. The specification must be enabling as of the filing date. See MPEP 2164.05(a).

In response to applicant's argument that US Patent No. 6,602,705 has been issued with claims and disclosure highly analogous to those in the pending claim, the difference being that US Patent '705 claims polynucleotide sequences subtype C sequences and the guidance provided by this issued Patent regarding homology and assaying immunogenicity is virtually identical to

that provided in the pending specification. Thus, '705 an issued and presumptively valid US Patent provides further evidence that the Patent Office considers claims such as those pending herein to be adequately described.

Applicant's argument is not found persuasive because every case is decided on its own merits. *See In re Giolito*, 530 F.2d 397, 400, 188 USPQ 645, 648 (CCPA 1976):

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 5-11, and 19-21 remain provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 16-22, and 30-32 of copending Application No. 10/190,435. Both sets of claims are directed to an expression cassette comprising a polynucleotide sequence encoding an HIV polypeptide and cells comprising the expression cassette. The polynucleotide sequence SEQ ID NO: 9 in the claims of '435 has at least 90% sequence identity to SEQ ID NO: 30-32 in the instant claims. (99.2% sequence identity with SEQ ID NO: 32). Furthermore, the limitations in instant claims 5-11 and 19-21 are the same as the limitations recited in claims 16-22 and 30-32 of '435.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Applicant's arguments filed 7/21/06 have been fully considered but they are not persuasive because the applicant request the provisional rejection be held in abeyance until indication of allowable claims in one of the applications.

NOTE: It appears that application 10/190,435 is in condition for allowance and when '435 issues as a US patent the provisional odp rejection will become an odp rejection.

Conclusion

Claims 48-51 are free of the prior art of record.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, SPE – Art Unit 1635, can be reached at (571) 272-4517.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman